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Office of Regulatory Policy
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5600 Fishers Lane (Rockwall II Rm 1101)
Rockville, MD 20857

Attention: Beverly Friedman

The attached application for patent term extension of U.S. Patent No. 5,571,182 was filed on December 20, 2006, under 35 U.S.C. § 156. Please note that the Applicant also filed patent term extensions based on the approval of PMA P040050 in U.S. Patent No. 5,336,263 and U.S. Patent No. 5,258,028, pursuant to 37 CFR 1.785.

Furthermore, Applicant's original application contained certain informalities for which a notice was mailed on July 10, 2007. Applicant has overcome the informalities with their submission of September 6, 2007 (re-submitted by request on September 18, 2007), a copy of which is attached hereto.

The assistance of your Office is requested in confirming that the product identified in the application, Macroplastique® Implants, has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Mary C. Tull
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